## REMARKS

### I. Interview

Applicant graciously thanks the Examiner for granting a personal interview with Applicant on January 9, 2006. During the interview, Applicant addressed the Jackson and Dorothy references in light of the claims. The issue of withdrawn claims was also discussed. Applicant agreed to submit the present response and declaration to the Examiner for consideration.

### II. Claim Amendments

Applicant has amended claim 1 of the application to simplify the claim and replace "a heteroatom" with "oxygen" and "medium and long chain alkyl groups comprising 8 or more carbon atoms" with "alkyl groups comprising from 8 to 12 carbon atoms". Support for these amendments can be found in at least paragraphs 56 and 57 of the specification. Where appropriate, the wording of the remaining dependent claims has been amended for conformity with amended claim 1. Claim 106 has also been amended to delete "at least one hydroxyl ester." The amendments to the claims do not introduce new matter into the application.

### III. Examiner's Withdrawal of Claims

On March 21, 2003, the Examiner issued a restriction requirement which Applicant responded to, noting that the elected species would read on claims 1, 46-62, 70, 71, and 78-103. After Applicant filed an RCE in November of 2004, the Examiner issued an Office Action in which he withdrew claims 49, 53, 86-91, 93-98, and 100. He did not provide any explanation as to why these claims were being withdrawn.

Applicant believes that many of these claims are still pending and has not identified the claims as "withdrawn" in its status identifiers.

Further, Applicant provided new claims 105-134 in its Response to the Examiner's November 16, 2005 rejection. Once the Examiner received these new claims, he listed claims 111, 112, and 116-119 as being withdrawn in his July 12, 2006 Office Action, without explanation. Applicant has not identified these claims as "withdrawn" it its status identifiers because it believes that these claims should be properly pending. The Examiner has not provided any indication as to why these claims should be withdrawn. Thus, it is Applicant's assertion that the currently pending claims include claims 1, 46-49, 52-53, 59, 61-62, 70-71, 78, 82-85, 89-92, 95-100, 105-134.

## IV. Rejection under 35 U.S.C. § 103(a)

In the July 12, 2006 Office Action, the Examiner repeated his rejection of the claims under 35 U.S.C. § 103(a) as being unpatentable over UK Patent Application No. GB 2247171 to Jackson in view of UK Patent Application No. GB 2338651 to Dorothy, *et al.* Applicant respectfully submits that the amended claims are not obvious in light of these references.

Claim 1 of the application is directed to:

> An anti-microbial composition consisting essentially of:
> (i) at least one anti-microbial agent, wherein at least one of the anti-microbial agents is a first anti-microbial agent having a high surface tension of from 20 to 35 mN/m, and selected from the group consisting of (a) a quarternary ammonium compound having the general formula $R^1R^2R^3R^4N^+X^-$, in which one or two of the R groups are alkyl substituted by aryl or interrupted by aryl or a heteroatom and the other R groups are the same or different and are $C_1$ to $C_4$ alkyl groups, (b) a dialkyldimethylammonium compound wherein the two non-methyl alkyl groups are selected from medium and long chain alkyl groups comprising 8 or more carbon atoms, and (c) a benzalknoium halide or an aryl ring substituted benzalkonium halide,

(ii) at least one compound having a low surface tension of from 8 to 14 mN/m, and selected from the group consisting of silanes, soya lecithins, polydimethylsiloxanes, polydimethylhydroxysiloxanes, and mixtures thereof, and

(iii) at least one polar solvent, wherein in use the anti-microbial composition acts substantially to reduce or control the formation of microbial colonies on or at a surface to which the composition is applied.

**Proper Interpretation of the Transitional Phrase**

As the Examiner is aware, the transitional phrase "consisting essentially of" limits the scope of the claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s) of the claimed invention." MPEP § 2111.03. While Applicant is aware that "consisting essentially of" may be construed as equivalent to "comprising" for purposes of search and examination if there is not a clear indication of in the specification or claims of what the basic and novel characteristics actually are, that is not the case here. The claims and the specification of the current application very clearly indicate that the invention is a three component system having (i) at least one antimicrobial agent as defined in claim 1, (ii) a low surface tension material as defined in claim 1, and (iii) a polar solvent. This is very clearly set forth in claim 1 and at least paragraph 31 of the specification. When the claims are interpreted properly, the Examiner has failed to show a *prima facie* case of obviousness.

**No Reasonable Expectation of Success**

The law is clear that "[o]bviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion, or incentive supporting the combination." *ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984). In fact, MPEP § 2143.01 provides: "The mere fact that references can be combined or modified

does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990)" (emphasis added).

The Examiner has attempted to combine the teachings of the references without any suggestion in the art that such combination would be desirable. The references cited by the Examiner cannot be combined because the combination does not provide any evidence that a person of ordinary skill in the art would have had a sufficient basis for the required expectation of success. In fact, as will be explained below, the provision of a composition as claimed is contrary to the teaching of each of the two documents.

Jackson describes a disinfecting composition comprising (i) a quaternary ammonium compound, (ii) a chlorinated methyl substituted phenol and (iii) at least one aqueous monohydric alcohol, wherein the ratio of (i) to (ii) is between 4:1 and 1:1.5 (page 3, lines 17 to 22). The whole essence of the invention described in Jackson is that a synergistic anti-bacterial effect is achieved by this combination of materials. The skilled person using the teaching of Jackson as the starting point for producing a new anti-microbial composition would have considered it to be essential to use both (i) a quaternary ammonium compound and (ii) a chlorinated methyl substituted phenol in a ratio as specified in that document. Thus, the teaching of Jackson would have actively discouraged him from using one of these materials in the absence of the other. In other words, there is no motivation in Jackson to attempt to produce a composition comprising a quaternary ammonium compound as the only essential anti-microbial agent. There is also no disclosure or suggestion in Jackson of using a low surface tension material as defined in claim 1 of the present application.

The examiner has cited Dorothy as providing the features of the present invention that are missing from Jackson. Dorothy describes a composition for use as an antimicrobial agent. The only antimicrobial composition exemplified in Dorothy comprises (a) polymer composition (isopropanol, butyl acetate, sulphuric acid, polydimethylsiloxane), (b) surfactant composition (anionic surfactant, non-ionic surfactant, amphoteric surfactant, ethanol, preservative), (c) first anti-bacterial agent composition (5-chloro-2-methyl-4-isothiazolin-3-1-ones, 2-methyl-4-isothiazolin-3-ones, diethylene glycol), (d) second anti-bacterial agent composition (alkyldimethyl-benzylammonium chloride, diethylene glycol), and (e) water. This amounts to no less than fourteen separate components. Given this large number of components, there are numerous ways in which the person of ordinary skill in the art could have altered the teaching of Jackson in view of the teaching of Dorothy.

There is absolutely nothing in Dorothy or Jackson that would have motivated the skilled person to select polydimethylsiloxane in the absence of any of the other components of the compositions of Dorothy for inclusion in a new anti-microbial composition. In fact, the teaching of Jackson and Dorothy would have actively discouraged him from doing this. It is well known that polydimethylsiloxane is not itself an antimicrobial material. The skilled person would not, therefore, have contemplated replacing the second anti-microbial agent (the chlorinated methyl substituted phenol) used in the Jackson formulations with polydimethylsiloxane.

Additionally, the teaching of Dorothy is very clear that the properties exhibited by the compositions described therein result from the combination of components used. For example, the properties of the polymer composition are described at page 6, lines 6

to 10; page 7, line 28 to page 8, line 2; and pages 8, lines 8 to 11. These sections of text very clearly described the properties of the whole polymer composition and there is absolutely no suggestion that any of these properties could be obtained using just some or one of the components of the polymer composition. The properties that the surfactant composition provides to the anti-microbial composition are also described at page 8, lines 8 to 11. The skilled person reading Dorothy would have appreciated that it was necessary to use of a polymer composition as defined in that document together with the other components contained in the composition of the example of Dorothy in order to provide an anti-microbial composition having the properties described in that document. If the Dorothy document provided the skilled person with any incentive to modify the compositions of Jackson, it would have encouraged him to introduce both a polymer composition and a surfactant composition as used in the Examples of Dorothy into the compositions of Jackson. After all, this is all that is exemplified in Dorothy. The skilled person would have had no incentive to produce a composition containing a limited number of those components and most certainly would have had no expectation that a particularly useful anti-microbial composition could be obtained using just the three essential components specified in claim 1 of the present application.

In summary, there is nothing in Jackson and Dorothy that would have encouraged the skilled person to select the combination of a quaternary ammonium compound, a low surface tension material, and a polar solvent as the only essential components of an anti-microbial composition. The Examiner has cited Dorothy for the teaching of polydimethylsiloxanes in a liquid polymer composition despite the fact that there is no suggestion in the art that the polydimethylsiloxane of Dorothy can or should

be combined with the composition of Jackson. The claimed invention taken *as a whole* cannot be considered to be obvious without some reasonable expectation of success in that combination as taught or suggested by the prior art. This reasonable expectation of success is absent in the cited references.

The Examiner cannot base obviousness on what the skilled person in the art might try, but rather, must consider what the prior art would have led the skilled person in the art to do. There are endless possibilities of individual materials and combinations of materials from the composition of Dorothy that that could have been used to modify the compositions of Jackson. However, on the basis of the teachings of these documents, the skilled person would have had no expectation that any one single component or any mixture of components could be advantageously used in the absence of the other components described in Dorothy. There is simply no teaching in either reference that the use of a quaternary ammonium compound as the only essential anti-microbial compound in combination with polydimethylsiloxane and a polar solvent would have any expectation of success. Because the Examiner has not provided any likelihood of success based upon Jackson and Dorothy, a *prima facie* case of obviousness has not been satisfied.

**Unexpected and Surprising Results**

In addition, the compositions of the invention have advantageous properties that could not have been predicted from the teachings of Jackson and Dorothy alone or in combination. The most significant of these advantages are (i) the compositions of the invention have improved anti-microbial properties compared to identical compositions that do not comprise a low surface tension material; and (ii) the compositions of the

invention have a residual effect. The skilled person reading Jackson and Dorothy could not have predicted that a composition as now claimed could have these advantageous properties and address the shortcomings of the prior art.

Both of these advantages are very clearly illustrated by experiments that have been conducted on behalf of the Applicants. These experiments are summarized in the Attached Declaration of Dr. Ulrich Schwarz which is being submitted with this response and the Annexes attached to that declaration.

As discussed in paragraph 10 of the Declaration and described in more detail in Annex I, an experiment that was conducted to illustrate the residual antimicrobial effect of compositions of the invention. In this experiment, the composition of the present invention was applied to a bathroom surface in two passenger cabins in a cruiser liner. The surface was then cleaned on a daily basis using water only. The total microbial count on the surface was tested on the third and the seventh day after application of the composition. The results reported show that the compositions of the invention provided a residual antimicrobial effect, largely reducing or controlling the formation of colonies of microorganisms on a surface for up to a week (the limit of this experiment) after application of the composition even when that surface is washed daily with water.

Some further experiments to illustrate the residual antimicrobial effect of the compositions of the invention are described in Annex II and discussed in paragraph 11 of the Declaration. A composition of the invention was applied to a surface and allowed to dry on that surface. When the surface was dry, a protein solution was applied to the surface and was dried. The surface was then rinsed extensively with distilled water. The water rinsing removed most of the protein solution from the surface, but did not

remove the inventive composition from the surface. A comparative test was also carried out in which the same procedure was followed except that an anti-microbial composition that did not comprise a polysiloxane was used in place of the composition of the invention. In this comparative test rinsing extensively with distilled water did not remove the protein layer. These results indicate that a microbial biofilm would be unable to adhere to a surface treated with the composition of the present invention while it would be able to adhere to a surface treated with the comparative anti-microbial composition. This experiment illustrates the residual effect of the inventive composition in that in addition to killing microbes present at a surface at the time a surface is treated with the composition, further microbial biofilm formation at that surface is also prevented.

As discussed in paragraphs 12 to 15 of the Declaration, Annex I also reports a number of experiments that were conducted to illustrate the surprising and unexpected antimicrobial effect that is achieved by the combination of a quaternary ammonium compound and a low surface tension material, as defined in the claims of the present application, as compared to a quaternary ammonium compound in the absence of a low surface tension material.

In one of the experiments described in Annex I, cotton cloths were soaked in three compositions or deionised water (control). The three compositions were a solution of low surface tension material such as Clearco (a polysiloxane, similar to Dorothy), a solution of a quaternary ammonium compound and a solution of Clearco and the quaternary ammonium compound. The treated cloths were stored at room temperature until they were completely dry. Each of the dry pre-treated cloths and the control cloths were placed in Petri dishes filled with 5 mL of deionised water and left to

stand for 5 minutes. The washed cloths were then dried. Each dry, washed cloth was challenged with 300 µL E. Coli and allowed to completely dry at room temperature. When dry, the cloths were incubated at 37°C for 2 hours. Deionised water was then added to each Petri dish to elute surviving E. coli. The plates were evaluated for viable colony forming units.

These experiments confirmed that low surface tension polysiloxanes (similar to in the polymer composition of Dorothy) do not themselves have any antimicrobial activity. In the experiments conducted, the quaternary ammonium compounds (which are similar to one of the anti-bacterial materials used in Jackson) were effective only at concentrations of 1.5% and 0.07%, but not at 0.025%. However, when a low surface tension material was used in combination with a quaternary ammonium compound, the antimicrobial properties of the resulting composition were unexpectedly enhanced. In fact, when the low surface tension material was used in combination with the quaternary ammonium compound as claimed in the present invention, the composition was effective as an anti-microbial agent at concentrations of 2.5%, 1.5%, 0.125%, 0.07%, 0.042%, and even 0.025%. These results were confirmed in a second experiment, which tested the compositions over a broader concentration range.

In summary, these experiments clearly show that the composition of the present invention is unexpectedly more effective as an anti-bacterial agent than the quaternary ammonium compound alone. It is especially surprising that a low surface tension material, which does not have any antimicrobial effect itself, enhances the antimicrobial effect of the quaternary ammonium compound.

In conclusion, the experimental results reported in the Declaration and its Annexes illustrate both the surprising and unexpected residual effect of the compositions of the invention and the surprising and unexpected enhanced antimicrobial effect that is achieved by the combination of a quaternary ammonium compound and a low surface tension material in a polar solvent. The skilled person could not have predicted that the claimed composition would have this combination of advantageous properties on the basis of the two cited prior art documents when considered alone or in combination.

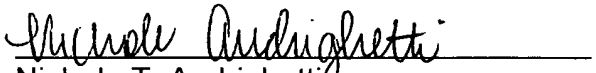
In view of the foregoing arguments, we respectfully submit that the rejected claims are patentably distinct over the references cited by the Examiner and meet all other statutory requirements. We believe that the present Application is now in complete condition for allowance and, therefore, respectfully request the Examiner to reconsider the rejections in the Office Action and allow this Application.

We invite the Examiner to telephone the undersigned should any issues remain after the consideration of this response. Please charge any additional fees that may be required to Deposit Account No. 50-2548.

Respectfully requested,

NELSON MULLINS RILEY & SCARBOROUGH

April 13, 2006
Date



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